

Group IV: Claims 20-23, drawn to genetically recombinant virus expressing polypeptide, classified in class 424, subclass 199.1;

Group V: Claims 24-31, drawn to method of producing immune cells directed against HSV cells presenting, classified in class 435, subclass 325;

Group VI: Claim 32, drawn to method of enhancing proliferation of HSV specific T cells, classified in class 435, subclass 343.2;

Group VII: Claim 37, drawn to method of treating or preventing an HSV infection, classified in class 536, subclass 23.74.

Group VIII: Claim 38, drawn to method of enriching a population of T cells specific to a virus, classified in class 435536, subclass 69.1.

Within Groups II through VII, the Examiner further required an election of a single sequence identified by a specific sequence identification number or a polypeptide.

In response, Applicants elect Group II, namely claims 7-12, 33 and 35, drawn to pharmaceutical compositions comprising an HSV U<sub>L</sub> 26 polypeptide and methods of use, with traverse.

35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative history of anything contrary to this interpretation as support for their position that "and" means "or". Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of the claim groups listed above are independent. Rather, the Examiner alleges that the inventions of the claim groups listed above are distinct because each are structurally and functionally different products and methods which are substantially different. Applicants assert that restriction is improper because all of the claims relate

to the common inventive concept arising from the discovery of a means by which HSV-2-specific lymphocytes in the blood become programmed to traffic to the skin during episodes of recurrent HSV-2 infection. Specifically, these T-cells have been found to express the glycoprotein molecule termed CLA (cutaneous lymphocyte-associated antigen). The invention makes use of this discovery to provide a method to purify HSV-2-specific T-lymphocytes from the blood that are HSV-2-specific based on sorting blood cells by a set of criteria that include the surface expression of CLA, CD8, and the co-stimulatory molecule CD28. This provides a method of rapid and efficient isolation of HSV-2-specific CD8 T-cells from blood. After obtaining these rare cells from the blood, the exact epitopes encoded by the HSV-2 genome, that are recognized by these HSV-2-specific CD8 T-cells, can be identified, providing HSV antigens and epitopes that are useful for the prevention and treatment of HSV infection. Applicants urge the Examiner take into consideration that the subject matter of each of the claim groups is linked by this common inventive concept.

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met.

Applicants assert that a search into prior art with regard to the invention of the different groups is so related that separate significant search efforts should not be necessary. For example, a search finding that the method of claim 1 is novel and nonobvious should provide the necessary information for examination of all of the claims dependent thereon as well as the method of claim 38 (which relates to the same method steps based on the isolation of CLA+ PBMC from an infected subject) without requiring an additional search effort. Likewise, separate significant search efforts should not be necessary to examine all of the compositions of matter and methods that relate to the identification of novel, immunologically significant HSV epitopes. Accordingly, there is no serious burden on the Examiner to collectively examine the claim groups listed above. Therefore, restriction is not proper under M.P.E.P. §803.

Consequently, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement. At the very least, Applicants request the Examiner consider rejoinder of appropriate claim groups upon identification of allowable subject matter and recognition that significant additional search and examination efforts would not be required.

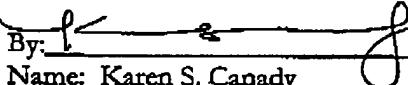
It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP  
Attorneys for Applicant(s)

Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, California 90045  
(310) 641-8797

Date: September 23, 2004

By:   
Name: Karen S. Canady  
Reg. No.: 39,927

KSC/amb